

## **Remarks**

### **I. The Interview**

Applicants appreciate the interview granted on September 1, 2004 by Examiners Dell Chism and Christopher Tate. Applicants agree with the content of the interview summary prepared by the examiner. In the interview, the relationship of the claims to issued claims in the patent family, the claims themselves, a fourth information disclosure statement to be submitted and declarations to be submitted were all discussed.

### **II. The Information Disclosure Statements**

Those IDSs were dated May 22, 2001; June 19, 2002; and March 10, 2003. Applicants previously submitted three information disclosure statements (IDSs) with associated 1449 forms in the present application.

The IDS dated March 10, 2003 has not been considered by the examiner. A copy of that IDS along with a copy of the postcard indicating its receipt by the Patent Office on March 13, 2003 are attached as Exhibit 1 hereto. The examiner is respectfully requested to consider that IDS along with this reply.

A fourth IDS is submitted herewith. Along with documents not previously submitted, the 1449 form for this fourth IDS re-lists Documents B31-B40, C24 and C26 which were originally included on the IDS dated June 19, 2002. The outstanding Office Action states that these documents were not considered by the examiner either because no English language translation was provided (B31-B40) or because a copy was not attached (C24 and C26).

The 1449 form submitted herewith indicates that B31 is a Japanese language equivalent of B20 that was previously considered by the examiner, B35 is a Japanese language equivalent of B23 that was previously considered by the examiner, B36 is a Japanese language equivalent of B49 submitted herewith, and B37 is a Japanese language equivalent of A32 submitted herewith. English language translations of B32-B34 and B38-B40 are submitted herewith. Copies of C24 and C26 are also submitted herewith. The examiner is respectfully requested to consider documents B31-B41, C24 and C26 as well as the new documents listed on the fourth 1449 form.

### III. The Outstanding Rejections

Claim 52 was objected to as purportedly being in improper form because it failed to refer to other claims in the alternative only.

Claims 50-51 were rejected under the judicially created doctrine of obviousness-type double patenting as being purportedly unpatentable over claim 6 of U.S. Patent No. 5,985,265 (the '265 patent); over claims 63-77 of co-pending U.S.S.N. 10/264,846 (the '846 application) in view of the '265 patent; over claims 1, 4 and 13-14 of U.S. Patent No. 5,770,577 (the '577 patent); and over claims 1-2 and 5-6 of U.S. Patent No. 5,795,569 (the '569 patent).

Claim 50-51 were asserted to be anticipated under 35 U.S.C. §102(e) by Karasiewicz et al., U.S. Patent No. 5,382,657 (the '657 patent).

### IV. The Amendment

New claims 54-65 are added by the amendment herein. The new claims do not introduce new matter and find support throughout the specification, for example, at page 7, lines 2-5; page 10, lines 6-9; and page 21, lines 12-23. Other examples of support of specific claim limitations include, but are not limited to, the following page and line numbers.

For “a monopolymer/protein conjugate” see page 10, lines 19-25; page 11, lines 3-14; and page 19, lines 18-29.

For “predominant” or “predominantly” see page 17, lines 11-12 and page 22, lines 15-17. As used therein and in claims 54-65, “predominant” and “predominantly” mean the most common or prevalent conjugate (claim 54) or site of conjugation (claim 65).

For “a hematopoietic protein” see page 11, lines 15-17 and page 24, line 32 through page 25, line 3. “Hematopoietic proteins” such as colony stimulating factors, erythropoietin and the like induce hematopoiesis, the proliferation and release of blood cells to the blood stream (see page 3, lines 25-28).

For “having one or more available epsilon amino reactive groups” see page 19, lines 2-9. For “a polyethylene glycopolymer moiety located at the N-terminus but not on an epsilon amino group” and “the polyethylene glycol polymer is conjugated via an alpha amino group” see page 19, lines 8-9 and lines 24-25.

For “prolonged *in vivo* biological activity” see page 25, lines 25-29 and Example 1, page 37, lines 14-22 (referring to Figures 5A and 5B).

For recited molecular weights of polyethylene glycol see page 14, lines 6-18 and page 21, lines 3-8.

For "a pharmaceutical composition" see page 24, lines 1-29.

Thus, the subject matter of claims 54-65 is described in the specification and the foregoing claim limitations distinguish the prior art cited by the examiner and the prior art made, or being made, of record herein.

#### V. Patentability of Claims 54-65

##### A. The Objection to Claim 52 May Be Withdrawn

The objection to claim 52 is may be withdrawn in view of the cancellation of claim 52. Furthermore, the objection should not be applied to new claim 65 because the claim refers in the alternative to previous claims.

##### B. The Provisional Rejections of Claims 50-51 May Be Withdrawn

The rejections of claims 50-51 may be withdrawn in view of the cancellation of those claims. To preclude any potential rejections of the new claims in view of the same patents and published application, submitted herewith as Exhibits 2-5 are terminal disclaimers with respect to the '265 patent, the '846 application, the '577 patent and the '569 patent.

##### C. The Rejection of Claims 50-51 under 35 U.S.C. §102(e) May Be Withdrawn

The rejection of claims 50-51 as anticipated by the '657 patent may be withdrawn in view of cancellation of those claims. Moreover, the rejection should not be applied to new claims 54-65.

The '657 patent does not describe or suggest a hematopoietic protein conjugated to a polyethylene glycol polymer moiety as is recited by claims 54-65.

#### VI. Change in Inventorship

Submitted herewith as Exhibit 6 is a request to change inventorship under 37 C.F.R. §1.48(b). The names of two inventors, Olaf B. Kinstler and Randolph B. De Prince, are being deleted because prosecution of the application has resulted in cancellation or amendment of claims so that the two are not inventors of the invention now being claimed.

VII. Submission of Declaration Under 37 C.F.R. §1.131

Submitted herewith as Exhibit 7 is a declaration under Rule 131 that provides facts that establish the invention of the subject matter of claims 54-65 prior to October, 1993. Applicants are submitting the declaration to antedate Documents A35, A37, A38, A40, C63, C81, C92, C94 and C95 which were all dated October 1, 1993 or later.

VIII. Conclusion

New claims 54-65 are thus believed to be recite patentable subject matter and early notice of the same would be appreciated.

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Respectfully submitted,

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